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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT PAPER NUMBER

3738

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/775,034

Applicant(s)

DEPUY MITEK INC.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8, 11, 12, 19, 22, 23, 29, 32, 33, 40 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 10, 13-18, 20, 21, 24-28, 30, 31 and 34-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/7/04, 7/27/05, 3/13/06</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 7,8,11,12,19,22,23,29,32,33,40,41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/22/06. The traversal is on the ground(s) that Species E should only include the Figures represented in Figs 5A and 5C only excluding Fig. 5B. This is found persuasive and Fig. 5B is thus not grouped with Species E. The Applicant also traversed the establishment of Figs. 6 and 7 as Species. This is not found persuasive because the specification or disclosure presents three species of surface features for the device. These include: 1) a smooth or no surface feature as shown in the five species of composites of Figs. 1-5A,5C, a second species 2) Fig. 6 and a third species 3) Fig. 7. The Examiner would like to clarify the species requirement by not grouping the surface features with the composite structures but as separate species as mentioned above and is considering the elected surface feature to be smooth or no external features.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,5,6,13-15,17,18,24,25,27,28,34-36 are rejected under 35

U.S.C. 102(b) as being anticipated by Kuslich (5571189). Fig. 2 shows an implant **40** formed of a porous material (col. 7, lines 34,35). Kuslich discloses the material can be absorbable and a polymer, col. 7, lines 40,41,51. Kuslich additionally discloses the implant is filed with bioactive tissue, such as bone material or hydroxyapatite, col. 7, lines 13-20. Fig. 50 shows the implant can have top and bottom (**160,162**) respectively and are mated to one another, col. 11, lines 20-22. Kuslich also discloses the method of implanting the device in a defect site, col. 12, lines 29-35.

Claims 1-6,9,10,24-28,30,31 are rejected under 35 U.S.C. 102(b) as being anticipated by Yi et al. (2002/150604). Yi et al. disclose a method of repairing a tissue defect using a bioresorbable polymeric tissue material and a pocket to contain tissue material, page 1, paragraphs 10-20. Yi also discloses the polymeric material can be synthetic, paragraphs 30,34. The use of “substantially wedge-shaped” is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. Since Yi et al. disclose the bag can be any shape (paragraph 28), it can be construed that the implant is “substantially wedge-shaped”. Yi additionally discloses to incorporate a bioactive material in the implant pocket, paragraphs 48-50. Since the device has within its central area the tissue material it can be construed that above and below the tissue material are top and bottom portions of the scaffold. Yi also discloses the scaffold is porous and in a bag form and thus it can

be construed it has a pocket or lumen or hollow interior, paragraph 31. Yi also discloses that tissue, such as collagen can be used as the fill material for the pocket in the implant, paragraphs 43,47.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-18,20,21,34-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yi et al. (2002/150604). Yi et al. is explained supra. However, Yi fails to disclose the collagen materials are prepared in minced, sliced or slivered form. It would have been an obvious matter of design choice to modify the preparation of the collagen material, since applicant has not disclosed that using minced, sliced or slivered forms of tissue material provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the form of collagen tissue taught by Yi et al. or the claimed minced, sliced or slivered in claim(s) 13,34 because both implants perform the same function of providing an implant having biocompatibility and are effective to stimulate cell growth.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (6:30am-4pm) and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

